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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,513	08/16/2001	Keith G. Copeland	97,008-W	5062

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MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
SUITE 3200
CHICAGO, IL 60606

EXAMINER	
BEX, PATRICIA K	

ART UNIT	PAPER NUMBER
1743	9

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/931,513	COPELAND ET AL.	
	Examiner	Art Unit	
	P. Kathryn Bex	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72,73,76,77,80-87,89-91,94,98 and 99* is/are pending in the application.

4a) Of the above claim(s) *76,86 and 94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72,73,77,80-85,87,89-91,98 and 99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 72-73, 77, 80-85, 87, 89-91, 98-99 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. .

Claim 72, recites dispensing a reagent onto either the support medium or the evaporation inhibiting liquid phase. It is not clear as to how the sending a stream of air to move the evaporation-inhibiting liquid phase and stir the reagent with the biological sample would be accomplished if the reagent is dispensed onto the support medium and does not contact the evaporation-inhibiting phase. The instant claim does not require the reagent contact the evaporation inhibiting liquid phase, therefore it is not possible to clearly define the metes and bounds of the invention as claimed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 72, 77, 80-81, 84-85, 87, 89, 91, 98 are rejected under 35 U.S.C. 102(b) as being anticipated by Mazza *et al* (USP 4,815,978).

Mazza *et al* anticipate the method substantially as claimed. Mazza *et al* teach clinical analysis methods of liquid biological samples. The method comprising the steps of; dispensing a reagent tablet in cuvette 24, then dispensing an aqueous diluent 52 into the cuvette. Next, adding biological sample into the cuvette from sample dispenser 80. Then, adding a second reagent from a dispensing station 54 into the cuvette (column 7, lines 2-9). Lastly, an air jet mixing apparatus 15a provides for thorough remixing of the cuvette contents following the addition of the second reagent at station 54. The air jet J is directed an acute angle at the junction of the liquid surface in the cuvette such that the air jet hits the meniscus at this junction. A vortex is created with produces a through mixing of the contents of the cuvette. This mixing is such that even a reagent which is immiscible in the diluent becomes totally suspended with the diluent and the reaction between the reagent and the sample is more complete and rapidly achieved (column 8, lines 38-47, Figs.1-2, 4-5, 9-10).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 90, 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza *et al* (USP 4,815,978) in view of Swope *et al* (USP 5,350,697).

Mazza *et al* as previously discussed above do teach the use of a cuvette as the support medium of the reagents and sample. However, Mazza *et al* do not teach the use of a microscope slide. However, the substitution of a microscope slide for a cuvette is considered conventional in the art, see Swope *et al*. Swope *et al* do teach an apparatus for use in immunoassay comprising the use of a receiving means for receiving samples and reagents. Swope *et al* teach the equivalence of slide and cuvettes as receiving means for optical analysis in immunoassay art (column 3, lines 27-45).

Accordingly, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the claimed invention to have substituted the cuvette of Mazza *et al* with a microscope slide, since applicant has not disclosed that the use of a microscope slide solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the cuvette of Mazza *et al*.

Response to Arguments

9. Applicant's arguments filed October 23, 2002 have been considered but have not been found persuasive. With respect to the previous rejection of claims 72, 77, 80, 84-85 under 35 U.S.C. 102(b) as being anticipated by Mazza *et al* (USP 4,815,978), Applicant argues that Mazza *et al* teach the use of cuvette not a support medium. This argument is not germane to the issue since applicant has not excluded a cuvette from claim 72. Additionally, Applicant argues that Mazza *et al* do not teach the use of an evaporation-inhibiting liquid or the use of the indirect method of mixing the reagent with the biological sample via an air jet. Examiner does not agree since Mazza *et al* do teach adding a second reagent (e.g. evaporation-inhibiting liquid) from a dispensing station 54 into the cuvette (column 7, lines 2-9). Then directing an air jet an acute angle at the junction of the liquid surface in the cuvette such that the air jet hits the meniscus at this junction. A vortex is created with produces a through mixing of the contents of the cuvette. The second reagent is considered an evaporation-inhibiting liquid since office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. No specific disclosure as to the composition, or properties, of the evaporation-inhibiting liquid are within the claims. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also *In re Zletz*, 893 F.2d 319, 321-22, 13USPQ2d 1320, 1322 (Fed. Cir. 1989).

Conclusion

10. No claims allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
March 18, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700